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Robert J. Baran  
Allergan, Inc.  
2525 Dupont Drive  
Irvine, CA 92612

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,688,819

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,688,819, which claims the method of use of the human drug product, LUMIGAN® (bimatoprost), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 698 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 698 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of January 28, 2004 (69 Fed. Reg. 4170). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,787 - 752) + 180 \\ &= 698 \text{ days (1.9 years)}\end{aligned}$$

Since the regulatory review period began October 29, 1995, before the patent issued (November 18, 1997), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From October 29, 1995 to and including November 18, 1997 is 752 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,688,819
Granted:	November 18, 1997
Original Expiration Date <sup>1</sup> :	September 21, 2012
Applicant:	David F. Woodward et al.

<sup>1</sup>Subject to the provisions of 35 U.S.C. § 41(b).

Owner of Record: Allergan, Inc.

Title: CYCLOPENTANE HEPTANOIC ACID, 2-CYCLOALKYL OR ARYLALKYL DERIVATIVES AS THERAPEUTIC AGENTS

Classification: 514/357

Product Trade Name: LUMIGAN® (bimatoprost)

Term Extended: 698 days

Expiration Date: August 20, 2014

Any correspondence with respect to this matter should be addressed as follows:

By mail:      Commissioner for Patents                          By FAX:      (571) 272-7744  
                  Mail Stop Patent Ext.                                 Attn: Office of Patent Legal Administration  
                  P.O. Box 1450  
                  Alexandria, VA 22313-1450

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7744.

Karin Ferriter  
Karin Ferriter  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc:      Office of Regulatory Policy  
            HFD - 13  
            5600 Fishers Lane  
            Rockville, MD 20857

Attention: Claudia Grillo

RE: LUMIGAN® (bimatoprost)  
FDA Docket No. : 03E-0037